

## **REMARKS/ARGUMENTS**

A Request for Continued Examination accompanies this response.

### **Telephone Interview Summary**

A telephone interview was conducted with the Examiner on 11 November 2008. The Examiner's interpretation of claim 1 with regard to the cited prior art was discussed. The Examiner stated that more detail in claim 1 regarding the working head and the relationship between the guidewire and the working head would help to clarify the distinguishing features of the present invention over the prior art.

### **In the Claims**

Claims 1-31 remain in this application. Claims 1, 4 and 16 have been amended.

### **§ 103 Rejections**

The Examiner has rejected claims 1-13, 16-25, 28 and 30-31 under 35 U.S.C. 103(a) as being unpatentable over McKenzie et al. (5,993,469) in view of Pomeranz (US 5,938,609) and in further view of Selmon et al. (US 2001/0018596 A1); claim 29 is rejected in further view of Findlay (6,623,495); and claims 14, 15, 26 and 27 in further view of Masch (4,728,319). The Examiner's rejections are respectfully traversed.

Applicant relies on arguments presented in previous papers regarding the differences between the present invention and the cited prior art. Further, Applicant respectfully asserts that none of the McKenzie et al., Pomeranz, Selmon et al., Findlay or Masch teach a combination of an imaging guidewire and catheter as taught by the present invention.

The present invention clearly teaches imaging guidewire insertable in the lumen of a blood vessel up to intraluminal plaque without traversing the plaque. The imaging guidewire is configured with a distal tip that includes imaging components capable of generating digital data which describe a cross-sectional image of the lumen and communicating the digital data to a central processing unit (CPU). Further, the imaging guidewire is capable of guiding a catheter to the intraluminal plaque without traversing the plaque. The catheter includes a working head designed and constructed to remove at least a portion of the intraluminal plaque. The working head is deployed on the imaging guidewire

so as to accept passage of the imaging guidewire axially through a central region of the working head and the catheter as the catheter is propelled towards the intraluminal plaque until the catheter reaches a distal tip of the guidewire such that only a portion of the imaging components extend in front of the working head.

This combination is clearly taught in Figures 1, 4a-6 and 15 and in the specification on page 16, the second paragraph,

“...The distal end of imaging guidewire (16) comprises a folding mirror (17) that is optically coupled to a grin lens (18), and a preformed curved tip transparent to light energy (20) that encapsulates the folding mirror (17). In some embodiments of the invention the folding mirror (17) and the grin lens (18) protrude in front of the working head. In the preferred embodiment, shown in FIG. 1, only folding mirror (17) protrudes in front of the working head. This design minimizes the trauma to the blood vessel. It is an important feature of the present invention that the angle between folding mirror (17) and the catheter axis may vary, thus enabling the image to be taken at cross sections distally or proximally to the folding mirror (17). In the arrangement shown in FIG. 1 the angle is 45 degrees and therefore the image is taken at the section of the folding mirror (17). An optical fiber (19) is optically coupled to the grin lens (18). The optical fiber (19) extends, via a central lumen, all over the imaging guidewire (16) up to the proximal end where it is coupled to an optical connector (not shown in drawing)...” (emphasis added)

in the last paragraph on page 19,

“...FIG. 5 shows an imaging guidewire (16) that has the same diameter (e.g., 350 microns) along its entire length. This small diameter guidewire includes a small diameter lens (18), as described in U.S. Pat. No. 6,445,939 to Swanson. This construction allows only a small part of the imaging guidewire (16) to protrude in front of working head (6). This minimizes the trauma to the blood vessel. The part that protrudes includes folding mirror (17) that is located in preformed curved tip transparent to light energy (20). Also are shown lens (18) and optical fiber (19). Imaging guidewire (16) rotates on a sliding surface (27). A ring (28) is fixed to distal end of imaging guidewire (16), thus preventing imaging guidewire (16) from being pulled back beyond sliding surface (27)...” (emphasis added)

and in the first paragraph on page 20,

“...FIG. 6 shows an alternative embodiment of the working head (6). The working head (6) has opening (7) on its distal surface. The distal end of imaging guidewire (16) is substantially bigger than its other parts. In order to reduce the part of the imaging guidewire (16) that extends in front of working head (6) a recess (29) is done in the front face of working head (6). This construction minimizes the trauma to

the blood vessel. The part that protrudes out of working head (6) front face includes only folding mirror (17) that is located in preformed curved tip transparent to light energy (20). Imaging guidewire (16) rotates on a sliding surface (27). Also are shown lens (18) and optical fiber (19). This embodiment has advantages when used for clearing total occlusions (22)..." (emphasis added)

The Applicant has new amended claims 1 and 16 to recite such a combination of imaging guidewire and working head.

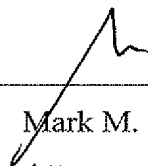
Further, Applicant asserts that there is neither hint nor suggestion in the cited prior art to provide the combination of imaging guidewire and working head as now claimed.

The Applicant believes that the above comments and amendments completely overcome the Examiner's rejections of claims 1 and 16 on §103(a) grounds, and therefore the rejections of claims 2-15 and 17-31, which depend therefrom, are now rendered moot.

In view of the above remarks, it is respectfully submitted that the claims are in condition for allowance.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,  
DR. MARK FRIEDMAN, LTD

By   
Mark M. Friedman  
Attorney for Applicant  
Registration No. 33,883

Date: November 19, 2008